UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------|------------------|
| 10/617,543 | 07/10/2003 | Harvey Ellis Cline | 124387 | 4286 |
| GENERAL ELECTRIC COMPANY GLOBAL RESEARCH PATENT DOCKET RM. BLDG. K1-4A59 NISKAYUNA, NY 12309 | | | EXAMINER | |
| | | | RAMIREZ, JOHN FERNANDO | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3737 | |
| | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 09/05/2008 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ldocket@crd.ge.com rosssr@crd.ge.com parkskl@crd.ge.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte HARVEY ELLIS CLINE, RONALD DEAN WATKINS, and JOHN FREDERICK SCHENCK

Appeal 2008-3572 Application 10/617,543 Technology Center 3700

Decided: September 3, 2008

Before ERIC GRIMES, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-15 as obvious over prior art. Jurisdiction for this appeal is under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claims are directed to methods of detecting iron in the brain using magnetic resonance imaging. Claims 1-15 are pending and stand rejected as follows:

Claims 1-3 and 6-13 under 35 U.S.C. § 103(a) as obvious over Bartzokis (US 5,322,682, issued Jun. 21, 1994) and '322 Jesmanowicz (US 5,603,322, issued Feb. 18, 1997) (Ans. 13); and

Claims 4, 5, 14, and 15 under 35 U.S.C. § 103(a) as obvious over Bartzokis, '322 Jesmanowicz, and '972 Jesmanowicz (US 6,294,972 B1, issued Sep. 25, 2001) (Ans. 9).

We select claim 1 as representative of the rejected subject matter to focus our analysis. Claim 1 reads as follows:

1. A method for detecting iron in the brain using magnetic resonance imaging (MRI) comprising:

generating a substantially high magnetic field strength within the MRI system;

acquiring magnetic resonance (MR) images at the substantially high magnetic field strength by a pulse sequence adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits; and,

characterizing regions of interest using the magnetic field maps to detect statistically relevant quantities of brain iron deposits to indicate a given disease.

ISSUE ON APPEAL

The Examiner's position is that Bartzokis teaches all the limitations of the claimed method, but not "a pulse sequence adapted to create a magnetic field map of the brain" as in claim 1. However, based on the teachings of '322 Jesmanowicz, the Examiner concludes that it would have been obvious to have modified Bartzokis's method to have made the claimed invention.

Appellants contend that the cited prior art does not teach all elements of the claimed invention (e.g., a magnetic field map) nor provide a reasonable basis for combining it to have made the claimed invention.

¹ "Ans." refers to the Answer mailed May 15, 2007.

Therefore, the issues in this appeal are: whether the Examiner erred in finding that all the limitations of claim 1 are disclosed or suggested by Bartzokis and '322 Jesmanowicz; and whether the Examiner erred in finding a reason to combine the cited prior art.

CLAIM INTERPRETATION

Claim 1 is directed to a method of detecting iron in the brain using MRI. The claimed method comprises three steps: 1) generating a high magnetic field strength; 2) acquiring MR images by a pulse sequence "adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits"; and 3) characterizing regions of the brain based on the magnetic field maps to detect "brain iron deposits". The magnetic field maps in step 3 "indicate a given disease."

The Specification defines "magnetic field map" to mean "measurements acquired during MRI to estimate the constant and linear components of the magnetic field inhomogeneity" (Spec 7: 26-28). Pulse sequences are utilized in step 2) to create the magnetic field map — apparently a result of the "constant and linear" field inhomogeneities associated with iron (*see* Ans. 11-12). The magnetic field map is used in step 3) to detect brain iron deposits and indicate disease.

Also in step 2), it is stated that the pulse sequence at high field strength is "adapted to create a magnetic field map of the brain for use in enhancing brain iron deposits." The claim does not use the close-ended phrase "consisting of" or any other term that would exclude other information from also being used to create the magnetic map. However, since the "magnetic field map" is defined in the Specification to mean MRI measurements, any additional information utilized to create the map must be

from "measurements acquired during MRI" of magnetic field inhomogeneities (*see* Spec. 7:26-28).

OBVIOUSNESS OVER BARTZOKIS AND '322 JESMANOWICZ

Claims 1-3 and 6-13 stand rejected under 35 U.S.C. § 103(a) as obvious over Bartzokis and '322 Jesmanowicz.

Scope and Content of the Prior Art

The following findings of fact (FF) summarize the prior art cited by the Examiner (Ans. 3-8) in support of the rejection over Bartzokis and '322 Jesmanowicz.

THE BARTZOKIS PATENT

- 1. According to Bartzokis, iron has been implicated "as a central culprit" in various diseases, including neurological disorders, such as Alzheimer's and Parkinson's disease (Bartzokis, at col. 1, ll. 14-23).
- 2. Bartzokis states that the "noninvasive use" of MRI "to measure iron stores" was "well known", but acknowledges that the reliability of prior art methods were not "universally accepted" or "well established" (Bartzokis, at col. 1, 1l. 47-50).
- 3. Bartzokis summarizes reports in the scientific literature describing the correlation between T_2 relaxation and iron levels in the brain (Bartzokis, at col. 2, 11. 8-42).
- 4. Based on the prior art, Bartzokis concludes that it was "known that the enhancement of iron-related contrast as seen in magnetic resonance images" was dependent on field strength, although this field dependence had not been used to quantify iron stores (Bartzokis, at col. 3, Il. 7-11).

- 5. Bartzokis characterizes its invention as providing "a specific measure of iron stores in vivo using" MRI (Bartzokis, at col. 5, ll. 7-8) for use in clinical studies to monitor and evaluate diseases (*id.* at col. 11, ll. 30-66).
- 6. By performing MRI scans of the brain at two different field strengths, Bartzokis states that tissue iron concentrations can be measured and displayed as a two- or multi-dimensional map (Bartzokis, at col. 5, 1. 57 to col. 6, 1. 7).

7.

The T_2 of tissue in both lower-to-mid field strength magnetic resonance imaging instruments and a higher field strength instrument is evaluated. T_2 obtained by the higher field strength instrument is subtracted from T_2 obtained by the lower field strength instrument . . . This difference, T, obtained in vivo is then correlated with a quantitative measure of the iron stores in vivo in the scanned tissue. A two-dimensional or multidimensional map of the scanned tissue is then constructed on the basis of T.

(Bartzokis, at col. 5, 11. 8-18; see Ans. 4.)

- 8. In the examples, Bartzokis describes using "Carr Purcell Meiboom Gill two spin-echo sequences" for its MRI scan (Bartzokis, at col. 9, ll. 4-6) (Ans. 13).
- 9. The MRI scans are utilized by Bartzokis to assess iron stores in different regions of the brain (Bartzokis, at col. 9, l. 15 to col. 10, l. 68).

THE '322 JESMANOWICZ PATENT

10. '322 Jesmanowicz describes NMR pulse sequences to acquire MRI brain images (Ans. 4; '322 Jesmanowicz, at col. 2, ll. 40-60).

Differences between the Prior Art and Claim 1

11. Bartzokis teaches a method of measuring "iron stores" in the brain utilizing MRI scans performed at "high" (and "low") field strengths (FF5-7),

and thus meets the limitations of claim 1 of 1) "generating a substantially high magnetic field strength" and 2) "acquiring" magnetic resonance images at the high magnetic field strength (*see* Ans. 4).

- 12. Bartzokis also describes producing a map of the field strength information to measure and display tissue iron concentrations (FF6, 7), meeting the additional element of claim 1 of creating a "magnetic field map of the brain for using in enhancing brain iron deposits" (*see* Ans. 4, 10-12).
- 13. The maps are utilized by Bartzokis to detect iron deposits in different regions of the brain for the clinical study of diseases (FF5, 9) as in the last step of claim 1 in which "regions of interest" of the brain are characterized "to detect . . . quantities of brain iron deposits to indicate a given disease".
- 14. Bartzokis does not specifically disclose acquiring "images by a pulse sequence" as in the second step of claim 1.

Level of Ordinary Skill in the Art

15. Persons of ordinary skill in the art know to perform MRI scans using pulse sequences (*see* FF10).

Reason to Combine the Prior Art

16. The Examiner finds that persons of ordinary skill in the art would have been prompted to combine '322 Jesmanowicz's teaching about image acquisition using a pulse sequence with Bartzokis's method of measuring iron stores "to provide a better method for iron detecting in a selected region" (Ans. 4).

Analysis

The Examiner finds that Bartzokis describes all the steps of the claimed method for detecting iron in the brain (FF11-13), but does not teach the claimed "pulse sequence" for creating a magnetic field map (FF14).

However, the Examiner finds that, as evidenced by '322 Jesmanowicz, persons of ordinary skill in the art would have been prompted to have utilized pulse sequences "to provide a better method for iron detecting in a selected region" (Ans. 4) (FF 15, 16). Based on this evidence, the Examiner concludes that the subject matter of claim 1 is obvious.

Obviousness requires a teaching or suggestion of all the elements of the claimed invention and a reason as to why persons of ordinary skill in the art would have combined the prior art to have arrived at the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As the Examiner has identified all the elements of the claimed method in Bartzokis and '322 Jesmanowicz, and a reason to combine them, we conclude that prima facie obviousness of the claimed invention has been established. Thus, we turn to Appellants' rebuttal arguments and evidence.

Appellants argue that "the Examiner has not presented any evidence that discloses or suggest that the Bartzokis or '322 Jesmanowicz systems or methods employ a 'magnetic field map' as recited in the claims" (App. Br.² 5).

This argument is not persuasive. The Examiner cited express teachings in Bartzokis of using magnetic field strength differences to construct a two- or multi-dimensional map of iron stores (FF6, 7; Ans. 4; *see* also Final Rej'n 5³). The Bartzokis maps are made from MRI measurements and therefore meet the claimed limitation of a "magnetic field map" as defined in the Specification (Spec. 7: 26-28; *see supra* "Claim Interpretation").

² "App. Br." refers to the Appeal Brief dated Jul. 9, 2007.

³ "Final Rej'n" refers to the Final Rejection mailed Feb. 24, 2006.

Appellants also contend that Bartzokis does not teach or suggest the claimed step of acquiring MR images at a high field strength by a pulse sequence to create a magnetic field map of the brain (App. Br. 5-6).

By contrast, the Bartzokis reference teaches taking MR images at two different field strengths and thus multiple imaging sessions. The Bartzokis method requires the image information from both the multiple imaging sessions in order to obtain iron information.

(*id*. at 6).

Apparently, Appellants have read claim 1 to be limited to creating magnetic field maps with only high strength MR fields and images captured in one session. However, as we have interpreted the claim, "acquiring" MR images "at the substantially high magnetic field strength by a pulse sequence adapted to create a magnetic field map of the brain" is open to the use of additional MRI measurements to produce the field map, including measurements made at a low field strength as taught by Bartzokis (*see supra* "Claim Interpretation"; FF6, 7). There are no words in claim 1 which would exclude this additional step from being performed. Consequently, Appellants' argument is not persuasive.

Furthermore, even were claim 1 to be interpreted as Appellants say it should be, we note that the prior art as summarized by Bartzokis teaches that the use of MRI to measure iron stores was "well known" (FF2, 3), although not at a high magnetic field strength. However, Bartzokis also teaches that it was "known that the enhancement of iron-related contrast as seen in magnetic resonance images" was dependent on field strength (FF4), providing a reason to have utilized a high magnetic field strength alone to collect MR images of iron stores.

Appellants also assert that '322 Jesmanowicz only discloses imaging the brain, and not producing maps as claimed (App. Br. 6). This argument has no merit. The Examiner has clearly relied upon Bartzokis for teaching the claimed magnetic field maps (FF11, 12).

Finally, Appellants argue there was no basis to combine Bartzokis with '322 Jesmanowicz. They state that "the Examiner's rejections are based not on explicit disclosures within the cited references but merely on the Examiner's unsupported opinion of the desirability to provide a better method for iron detection" (App. Br. 6).

This argument does not persuade us that the Examiner erred. The Examiner has provided an explicit reason as to why persons of ordinary skill in the art would have been motivated to combine the prior art (FF16). The modification suggested by the Examiner was within the level of skill in the art (FF15). Precise teachings directed to the specific subject matter of a claim are not required to reach a conclusion of obviousness. *KSR*, 127 S. Ct. at 1741. "[T]he teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references. . . . The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kahn*, 441 F.3d 977, 987-988 (Fed. Cir. 2006). In this case, the Examiner has provided a logical reason for combining the prior art; Appellants have not identified a flaw in the Examiner's reasoning.

For the foregoing reasons, we affirm the rejection of claim 1. Claims 2, 3, and 6-13 fall with claim 1 because separate reasons for their patentability were not provided.

Appeal 2008-3572 Application 10/617,543

OBVIOUSNESS OVER BARTZOKIS AND '322 & '972 JESMANOWICZ

Claims 4, 5, 14, and 15 stand rejected under 35 U.S.C. § 103(a) as obvious over Bartzokis, '322 Jesmanowicz, and '972 Jesmanowicz.

The Examiner contends that claims 4, 5, 14, and 15 are obvious over the combination of Bartzokis, '322 Jesmanowicz, and '972 Jesmanowicz (Ans. 9-10). Appellants do not separately argue the patentability of these claims nor do they identify a defect in the rejection other than those already discussed for the rejection over claims 1-3 and 6-13 (*see* App. Br. 7). Consequently, we affirm the rejection of claims 4, 5, 14, and 15 for the same reasons as set forth for claim 1.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Ssc:

GENERAL ELECTRIC COMPANY GLOBAL RESEARCH PATENT DOCKET RM. BLDG. K1-4A59 NISKAYUNA, NY 12309